IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Masahiro Endo et al.
Appl. No.:	10/535,034
Conf. No.:	3565
Filed:	December 16, 2005
Title:	DIALYSIS CATHETER SET AND METHOD OF USING SAME
Art Unit:	3767
Examiner:	Catherine Witczak
Docket No.:	DI-5966 (0112713-1362)

September 4, 2007

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In response to the final Office Action mailed June 5, 2007, and the Advisory Action mailed July 25, 2007, Appellants herewith request review of the arguments contained herein before the preparation and filing of an Appeal Brief.

1. Appellants have invented a dialysis catheter. The new catheter overcomes problems associated with the prior art, including leakage problems, as stated in the application as filed, and specifically in paragraphs [0008] and [0009]. The leakage is averted, and operation of the catheter is controlled, by an obstructor or insert inside the catheter. See application paragraphs [0015] and [0018]. Accordingly, the dialysis catheter has two pluralities of apertures, as recited in independent Claims 1 and 16, or a single plurality as recited in Claim 23, and an insert, also known as an obstructor, that fills a majority of the interior space defined by the catheter, including the apertures, depending on the positions of the obstructor. The obstructor is also taught and claimed as having apertures.

There are three principal rejections. Independent Claims 1, 16, and 23 are rejected in view of U.S. Pat. No. 6,190,371 to Paul Maginot et al. in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"); Claims 1 and 23 are also rejected in view of U.S. Pat. No. 5,106,376 to Pekka Mononen et al. in view of Johnson. Claims 1 and 16 are then rejected in view of U.S. Pat. No. 5,782,797 to Cyril Schweich, Jr. et al., also in view of Johnson. In each of the rejections, the principal reference teaches one aspect of the claimed invention and the rejection admits that the reference does not teach or suggest the claimed plurality of side apertures on the extraperitoneal end. In each case, the addition of Johnson is inappropriate

because the addition of Johnson would frustrate the purpose of the main reference or otherwise make the main reference work in a way contrary to the patient's best interest, e.g., hemodialysis would be made to last longer, an anesthetic would be delivered to the wrong area, or drugs would be delivered to the wrong location. In addition, even with the addition of Johnson, the references do not teach or suggest all the limitations of the claimed inventions.

2. Claims 1, 3, 8, 11, 14-24, and 26 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 6,190,371 to Paul Maginot et al. ("Maginot") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). The rejection cites Maginot as teaching a catheter 34 and an insert 2. Note that the claim requires apertures on both the catheter and on the insert. The rejection admits that Maginot does not teach or suggest the plurality of side apertures on the extraperitoneal end of the catheter. Office Action, p. 2, lines 17-18. The rejection then states that Johnson, Fig. 1, teaches apertures on the proximal end of an insert located inside a catheter, and that it would have been obvious to modify the catheter of Maginot with an insert having a plurality of apertures as taught by Johnson "since such a modification would allow for even more fluid distribution within the catheter." Office Action, p, 2, lines 19-22.

Applicants are unable to find any "insert (2)" in Maginot and assume that the Office Action refers to working catheter 42, as depicted in Maginot Figs. 3 and 7A. If this is not correct, then Maginot does not teach or disclose "insert (2)" and fails to teach or suggest the recited insert. This point was not clarified in the Advisory Action; however, no change has been made in the rejection, so Appellants will continue forward with the rejection as stated: Maginot's guide catheter 34 is advanced as the claimed catheter, with insert 42 as the claimed insert. The rejection then adds the apertures of Johnson, stating that it would be obvious to add the apertures of Johnson to the insert of Maginot. Office Action, p. 2, lines 18-19. The rejection states that modifying Maginot's catheter with Johnson's side apertures would "allow for even more fluid distribution within the catheter." Office Action, p. 2, lines 19-22.

Maginot and Johnson do not teach orifices on the both the catheter and the insert as claimed

Catheter 42 of Maginot has only two proximal orifices 48, 52 and two distal orifices, 50, 54. See Maginot, col. 8, lines 41-51, and Figs. 3. 5. and 7A. Since Maginot lacks side orifices, the Office Action then cites Johnson, Fig. 1, as teaching side orifices in an "expandable flowrate" catheter. Thus, according to the Office Action, only the insert would have a plurality of apertures on its proximal end. Office Action, p. 2, lines 19-22. However,

Claims 1 and 16 both require that both the catheter and the insert have a plurality of side apertures. Claim 23 requires that the obstructor tube have an intraperitoneal end and an extraperitoneal end, the extraperitoneal end having a plurality of side apertures and a portion having an increased diameter (emphasis added). Even the improper combination of Maginot and Johnson does not teach or suggest all these limitations. M.P.E.P. 2143.03.

Adding Johnson's apertures would frustrate the purpose of Maginot

Adding side apertures to Maginot would frustrate the purpose of Maginot's invention by allowing blood being withdrawn to mix with blood being returned. Thus, blood drawn from the vena cava that has not been dialyzed and is in need of dialysis would be mixed immediately with blood returned from the dialyzer that does NOT need further dialysis. The dialyzing procedure would be less efficient and would take longer for the patient. Shortening dialysis time and preventing this mixing is why Maginot has two separated distal orifices 50, 54. See col. 12, lines 23-34. Additional side orifices also increase the likelihood of leakage and would frustrate the purpose of Maginot's two valves 37, 39. See col. 13, lines 45-49.

Accordingly, the references do not teach or suggest all the limitations of the claims, and thus fail to make out a prima facie case of obviousness. M.P.E.P. 2143.03. As discussed, the prior art does not suggest the desirability of the combination, per M.P.E.P. 2143.01 (I), and the proposed modification renders the prior art unsatisfactory for its intended purpose, per M.P.E.P. 2143.01 (V). Both of these violate the basic requirements of a *prima facie* case of obviousness. M.P.E.P. 2143. For these reasons, and because the references do not teach or suggest all the limitations of the claims, the Office Action fails to make out a *prima facie* case of obviousness, and Claims 1, 3, 8, 11, 14-24 and 26 are allowable. In addition, other claims depending from independent Claims 1, 16 and 23 are also allowable, including Claims 2, 4-7, 9-10, 13, 25-30, and 45.

3. Claims 1, 2, 4, 5, 7, 9-10, 13, 23, 29, and 30 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,106,376 to Pekka Mononen et al. ("Mononen") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). Mononen discloses an epidural anesthesia catheter set 10, in which cannula tube 11, spinal cannula 20, and thin cannula tube 21 each have only a single distal opening. The reason for the single opening is clear, when viewing Figs. 2, 3, and 4, that is, accurate delivery of spinal anesthesia. This is also discussed in the specification, col. 4, lines 47-52, which states that the catheter delivers anesthesia to the patient's spinal space.

Claim 1, as noted above, requires both the catheter and the insert to have a plurality of apertures, which is not taught in the references. Claim 23 requires that the obstructor have an intraperitoneal end and an extraperitoneal end, wherein the extraperitoneal end has a portion having an increased diameter. The Office Action does not contend that the reference teaches these limitations. Accordingly, there is no prima facie rejection because the references do not teach or suggest all the limitations of the claimed inventions. M.P.E.P. 2143.03.

In addition, the prior art does not teach the desirability of the combination. The rejection admits that Mononen does not teach or suggest side apertures, and cites Johnson as teaching a plurality of side apertures. The rationale for the combination is that adding side apertures would allow for even more fluid distribution within the catheter. See Office Action, p. 3, lines 7-10. By reasoning similar to that for the rejection of claims over Maginot and Johnson, the use of side apertures is not suggested by Mononen and is clearly not appropriate for Mononen. Additional side apertures in Mononen's catheters 11 and 20 would add nothing, since these catheters are not in actual contact with the anesthetic. Adding apertures to catheter 21 would result in leakage of the anesthesia out of the catheter. This would result in placing anesthesia in inappropriate places, and might have the practical effect of failing to deliver sufficient anesthesia to the desired location, the patient's spinal space.

Accordingly, the prior art does not suggest teach all the limitations of the claims, and does not teach or suggest the desirability of the combination, per M.P.E.P. 2143.01 (I), since the proposed modification renders the prior art unsatisfactory for its intended purpose, per M.P.E.P. 2143.01 (V). All of these violate the basic requirements of a *prima facie* case of obviousness over Mononen and Johnson. M.P.E.P. 2143. Thus, the Office Action fails to make out a *prima facie* case of obviousness, and Claims 1, 2, 4, 5, 7, 9-10, 13, 23, 29, and 30 are allowable. In addition, other claims depending from independent Claims 1 and 23 are also allowable, including Claims 3, 6, 8, 14-15, and 24-28.

4. Claims 1, 6, 16, 25, 27, 28, and 45 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,782,797 to Cyril Schweich, Jr. et al. ("Schweich") in view of U.S. Pat. No. 5,735,831 to Kirk Johnson et al. ("Johnson"). The Office Action admits that Schweich does not teach a plurality of side apertures on an extraperitoneal end of the device, but that Johnson does so teach, adding that Johnson's extraperitoneal apertures "would allow for more even fluid distribution within the catheter." Office Action, p. 3, last four lines.

Even the improper combination of Schweich and Johnson does not teach or suggest all the limitations of the claims. Claim 1 requires both the catheter and the insert to have a plurality of side apertures and Claim 23 requires the obstructor tube to have an extraperitoneal end with a portion having an increased diameter and a plurality of side apertures. The Office Action does not contend that the reference teaches these limitations and thus fails to make out a prima facie rejection at least against Claims 1 and 23. M.P.E.P. 2143.03.

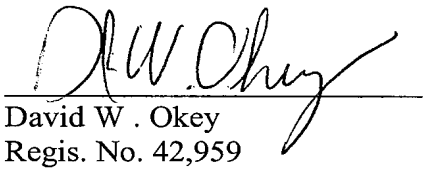
Adding extraperitoneal apertures that allow for more even fluid distribution within the catheter would allow the two drugs to mix with each other, or would allow the drugs to leave the catheter at a location other than the present two series of apertures. Either way, modifying Schweich with Johnson's additional extraperitoneal apertures would clearly frustrate Schweich's intention to deliver only one first drug to a desired first location and a different second drug to a desired and different second location. Col. 6, line 63 to col. 7, line 37.

By the same reasoning used above in the other rejections, the prior art thus does not teach or suggest all the limitations of the claims, per M.P.E.P. 2143.03, or the desirability of the combination of Schweich and Johnson, per M.P.E.P. 2143.01 (I), or that the proposed modification renders the prior art unsatisfactory for its intended purpose, per M.P.E.P. 2143.01 (V). All of these violate the basic requirements of a *prima facie* case of obviousness. Thus, the Office Action fails to make out a *prima facie* case of obviousness, and Claims 1, 6, 16, 25, 27, 28, and 45 are allowable. In addition, other claims depending from independent Claims 1 and 16 are also allowable, including Claims 2-5, 7-11, 13-15, and 17-22.

5. Appellants assert that the claims are allowable and respectfully request the Examiner to reconsider the rejections and to allow the claims of the application. Arguments specifically pointing out the patentability of the dependent claims are omitted in this paper for the sake of brevity. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

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